AMENDMENTS TO THE SPECIFICATION

Description of the Drawings

The invention is described in greater detail hereinafter relative to the drawing wherein:

Fig. 1 shows, in the lower graph, an infusion profile and, in the upper graph, the pattern resulting from this infusion profile of the quantity entered in the memory, the expected quantity (and therefore the concentration) of the active substance in the body of the patient, as well as the predetermined, permitted maximum value (threshold S);and

Fig. 2 illustrates an infusion pump of the present invention.

Detailed Description of the Preferred Embodiment

In the case of the infusion profile shown in Fig. 1 there is initially a long-term administration with a relatively low infusion rate. As from time t1 to t2 (caused by the patient or doctor) a first bolus administration takes place, i.e. a brief administration with a high infusion rate, such as is e.g. necessary if the patient suffers an acute attack. At time t3 switching to a higher infusion rate takes place. At time t4, using the control device, the administration of a bolus is brought about which, on reaching the predetermined threshold S is prematurely stopped at time t5 by the computer.

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At time t6 the user attempts to set a bolus administration, which is stopped at time t6 because the threshold S has been reached.

The path of the active substance concentration in the body of the patient resulting from this infusion profile and which is essentially proportional to the active substance quantity present in the body is shown in the lower graph.

The pattern of the active substance concentration is represented by a time integral over the infused quantity, reduced by the breaking down resulting from the half-life of the substance, i.e. as a function with a linear term determined by medicament administration and a negative exponential term determined by the medicament braking down rate.

In the drawing <u>of Fig. 1</u>, this leads up to time t1 to a constant path, because here the quantity supplied precisely corresponds to the quantity broken down by the body. The administration of the bolus at time t1 leads to a steep rise in the active substance concentration. At the end of bolus administration at time t2 the concentration continuously drops, because the supplied active substance quantity is lower than the broken down quantity. After doubling the infusion rate at time t3 the concentration constantly rises, but with a shallower rise.

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The bringing about of a further bolus administration through the user or doctor at time t4 leads to a concentration rise up to the threshold at time t5, which at time t6 leads to an automatic termination of bolus administration by the computer. The attempt at time t7 to bring about a further bolus administration is immediately prevented by the computer due to the immediate reaching of the threshold.

The path of the active substance concentration is simulated in the computer of the implantable infusion pump (which can also be located in the control device).

In predetermined time intervals, e.g. every 10 sec, the quantity entered in the memory of the infusion pump is increased by a quantity corresponding to the amount delivered by the infusion pump in this time period. Furthermore, a mathematically determined percentage of the quantity entered in the memory is subtracted from the half-life of the delivered medicament, the resulting quantity is stored as the actual value. Alternatively, in time intervals given by the half-life (i.e. more frequently with a shorter half-life and less frequently with a longer half-life), the amount delivered in this time period can be summed and a fixed quantity subtracted.

The value entered in the memory consequently always corresponds (due to the not precisely determinable half-life

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this is naturally only approximately) to the actual amount in each case or concentration of the active substance in the body of the patient, whilst taking account of the breaking down thereof.

Referring to Fig. 2, an infusion pump 10 for the delivery of an amount of a medicament to a patient's body is shown. Infusion pump 10 includes a first computer 12 which acts as an electronic control device for infusion pump 10. First computer 12 has a memory 14 and a comparator 16 which controls a blocking device 18 of infusion pump 10. Within memory 14 is stored a quantitative figure (not shown) which is a result of a summation of a total delivered medicament amount and a subtracting of a percentage of a quantity entered in memory 14 resulting from an expected breaking down of the medicament in the patient's body. Comparator 16 constantly compares the quantity entered in memory 14 with a pre-determined, permissible maximum value of the medicament. Since infusion pump 10 can be implantable, it is possible to have an external control device 20. In such embodiment, as shown in Fig. 2, a second computer 22 is provided for controlling external control device 20 whereas first computer 12 controls the implantable infusion pump 10.

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